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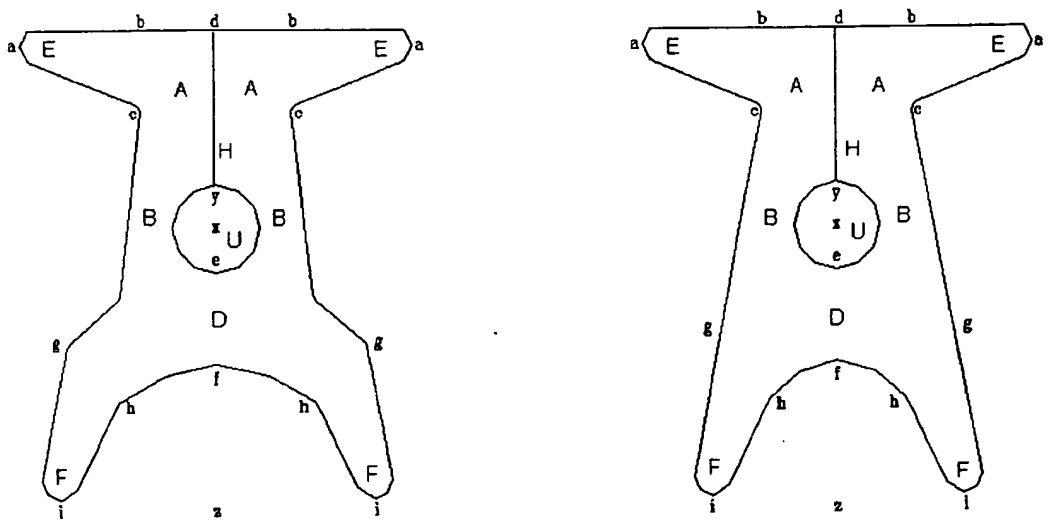
(54) Title: DEVICE FOR THE SURGICAL TREATMENT OF FEMALE PROLAPSE



(57) Abstract: A device is described having a reticular or laminar structure to be surgically implanted in uro-gynaecological treatments, useful in particular for the surgical treatment of total or partial prolapse of the female pelvic organs or of prolapse of the vaginal vault.

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DEVICE FOR THE SURGICAL TREATMENT OF FEMALE PROLAPSE

Field of the invention

The present invention concerns a device for supporting the female pelvic organs, to be surgically implanted in uro-gynaecological treatments.

State of the art

The term "female prolapse" means the sinking or displacement through the vagina of a female pelvic organ, bladder, uterus or rectum, which may occur for only one of these organs or for more than one organ simultaneously.

In the case where the prolapse concerns the bladder, there is protrusion of the front vaginal wall, known as "cystocele", in the case where the prolapse concerns the uterus, there is sinking of the upper vaginal wall, known as "hysterocele"; whereas the terms "enterocele" and "rectocele" are used when the vaginal wall affected by sinking is the rear wall and also comprises prolapse of the rectum.

When all the pelvic organs – bladder, uterus and rectum – are involved, the term used is "total prolapse" and in this case the whole vagina is affected by the sinking of the internal organs, to the extent that there is often a real evagination of the vagina.

In patients who have already had a hysterectomy, and are therefore without uterus, there may be "prolapse of the vaginal vault", in which sinking principally involves the bladder and the intestine.

Prolapse is a fairly frequent problem in women and may occur following a difficult vaginal birth or problems of the connective tissues.

Moreover, prolapse often appears in association with other disturbances, such as urinary or faecal incontinence. As may be easily imagined, female prolapse can therefore have important affects on the quality of life and may cause severe limitations in daily living.

While there may be various approaches to treatment for incontinence, even pharmacological, depending on the diagnosis, the treatment of female prolapse is exclusively surgical.

Up till now, in fact, the problem of female prolapse has been solved by surgically removing the uterus. The operation provides a remedy to the contingent situation

for a short time but, as it leaves an empty space where the removed organ had been, it increases the probability of sinking of other internal organs.

A further disadvantage is that surgical operations of this type require total anaesthesia of the patient, who will also require relatively long periods of hospitalisation and convalescence.

Devices have recently appeared on the market which, when surgically implanted, allow support of the urethra and of the neck of the bladder, and are therefore useful for correcting only urinary incontinence due to stress.

Summary of the invention

The Applicant has now found a reticular or laminar device which, when surgically implanted, provides support for the female pelvic organs in the case of prolapse of the vaginal vault or partial or total prolapse through the vagina.

This device therefore makes it possible to overcome the inconvenient aspects described above concerning the prior surgical technique: the device according to the invention may in fact be vaginally, mixed vaginally/abdominally or vaginally/laparoscopically implanted, or implanted by means of mini-invasive surgery, requiring in the majority of cases only local anaesthesia, the hospitalisation and convalescence times are considerably reduced and no organ is removed.

It is therefore subject of the invention a flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs, characterised in that it has a central body with a trapezoid shape having four arms, in which may be distinguished:

- a front portion corresponding to the smaller base of the trapezium, from the ends of which branch off in opposite directions two arms coaxial with each other and parallel to said smaller base;
- a central portion corresponding to the central part of the trapezium;
- a rear portion corresponding to the larger base of the trapezium, from the ends of which branch off two arms diverging from each other and parallel to the sides of the trapezium.

Brief description of the drawings

Figure 1: front view of the present device having a hole in the central portion and

the front portion divided into two halves by longitudinal cleft. Figures 1a and 1b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 2: front view of the present device having a hole in the central portion and the rear portion divided into two halves by longitudinal cleft. Figures 2a and 2b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 3: front view of the present device without the hole in the central portion and the longitudinal cleft. Figures 3a and 3b differ for dimensions, respectively adapted for bigger and smaller patient body sizes.

Figure 4: front view of the present device without the hole in the central portion and having the rear arms shorter than in the devices of Figures 1-3.

Detailed description of the invention

As a non limiting example of the invention:

- Figure 1a represents a front view of the device according to the invention constituted by a central body, in which may be distinguished a front portion A intended to hold the prolapsed bladder (cystocele), a rear portion D on which is placed the prolapsed intestine (enterocele), and a central portion B with the hole U which holds the uterus. The portions A, B and D into which the central body is subdivided are suitably shaped and have dimensions such as to be able to hold and support the prolapsed organs.

From the front portion A branch off the two arms E, while from the rear portion D branch off the two arms F; both pairs of arms are suitably shaped and positioned with respect to the longitudinal axis of the device in such a way that they can be anchored, during surgery, to fixed and well identified structures on the patient's pelvis.

In the device represented in Figure 1a the front portion A of the central body is divided into two halves by a longitudinal cleft H, the purpose of which is to divaricate during surgery the device already anchored through the rear arms F, so as to pass the two halves D from opposite sides with respect to the uterus and to be able to place the neck of the uterus more easily in the hole U.

- Figure 1b represents another front view of the device according to the invention, in which the dimensions, in particular those of the rear arms F and of the rear portion D, have been reduced to adapt the device to a smaller patient body size.

The present device may also be realised as in Figure 2a, with the longitudinal cleft H which cuts the rear portion D of the central body in two halves; this device adapts to a type of surgical implant in which the front arms E are anchored first, then the rear part D is divaricated thanks to the cleft H so as to facilitate the entry of the neck of the uterus in the hole U, and lastly the rear arms F are anchored.

Figure 2b represents the same type of device with the cleft H in the rear portion D shown in Figure 2a, in which the dimensions of the device have been reduced to adapt it to patients of a smaller size.

A further embodiment of the present device contemplates that the cleft H is present both in the front part and in the rear, thus cutting the device in two halves which are then rejoined at the time of surgery.

According to a further embodiment of the invention, the present invention has a central hole and a transverse cleft H which, starting from the central hole, cuts the central portion to the right of the hole, or the one to the left, in two halves.

Figure 3a represents the device according to the invention without the central hole U to be used, depending on the dimensions of the rear arms F described in greater detail below, in cases of prolapse of the vaginal vault in patients without uterus, or in cases of partial prolapse.

Figure 3b represents the same type of device for patients of a smaller size.

With reference to Figures 1-3, the dimensions of the device according to the invention are for example the following:

- length a-a of the front arms E: between 8.0 and 15 cm; when the device is implanted by means of "tension free" operations, the length a-a is typically between 11 and 15 cm, and is preferably 13 cm; while for all the other types of surgical implant it is typically between 8.0 and 12.0 cm and is preferably 10 cm;
- length b-b of the front portion A: between 2.5 and 6.0 cm, and preferably 3.8 cm;
- length c-c of the front portion A: between 3.0 and 6.0 cm, and preferably 3.8 cm;
- width b-c of the front arms E: between 1.0 and 3.0 cm and preferably 2.0 cm;
- length d-y of the front portion A: between 2.5 and 6.5 cm, and preferably 4.0 cm;

- total length d-z of the device: between 11 and 15 cm, and preferably 12 cm;
- distance y-x in the central hole U: between 0.6 and 1.6 cm, and preferably 1.1 cm;
- distance x-e in the central hole U, the same as or different from the distance y-x: between 0.6 and 1.6 cm, and preferably 1.1 cm;
- length e-f of the rear portion D: between 1.8 and 4.0 cm, and preferably 2.3 cm;
- width x-l: between 0.5 and 4.0, and preferably 2.5 cm;
- distance h-h between the rear arms F: between 1.5 and 7.0 cm; for devices to be implanted in patients of a small size it is typically between 1.5 and 5.5 cm and is preferably 3.5 cm, while for devices to be implanted in patients of a large size it is between 3.0 and 7.0 cm and is preferably 5.0 cm;
- distance g-g between the rear arms F: between 4.9 and 10 cm; for devices to be implanted in patients of a small size it is typically between 4.9 and 8.9 cm and is preferably 6.0 cm, while for devices to be implanted in patients of a large size it is between 6.0 and 10 cm and is preferably 7.6 cm;
- distance i-i between the rear arms F: between 4.5 and 10.5 cm; for devices to be implanted in patients of a small size it is typically between 4.5 and 8.5 cm and is preferably 6.5 cm, while for devices to be implanted in patients of a large size it is between 6.5 and 10.5 cm and is preferably 8.0 cm;
- length h-i of the rear arms F: between 2.5 and 6.5 cm, and preferably 4.5 cm.

The dimensions of the device according to the invention without a hole illustrated in Figure 4, are the same as given above for the embodiments illustrated in Figures 1-3, except for the length h-i of the rear arms and therefore for the total length d-z of the device.

In facts, the device illustrated in Figure 4, depending on whether it is to be implanted in patients with partial prolapse or in patients without uterus with prolapse of the vaginal vault, may have rear arms of different lengths.

A device suitable in the case of partial prolapse has for example the following dimensions:

- total length d-z of the device: between 4 and 8 cm, and preferably 5.1 cm;
- length h-i of the rear arms F: between 0.5 and 3 cm, and preferably 1.1 cm;

while the device suitable in cases of prolapse of the vaginal vault has the following dimensions:

- total length d-z of the device: between 10 and 13 cm, and preferably 11 cm;
- length h-i of the rear arms F: between 2.5 and 6.5 cm, and preferably 4.5 cm.

The device according to the invention must be made of a material having a reticular or laminar structure, so as not to retain exudates and organic liquids which could build up on the central body of device, in particular in area A.

Any material having a reticular or laminar structure, whether it be of organic or synthetic origin, is suitable for the realisation of the present device as long as it maintains its structure more or less unchanged over time and remains fixed in the position in which it was inserted during surgery.

Numerous synthetic materials are currently on the market which could be used to make the present device, for example materials based on single-filament polypropylene for use in surgical implants, in particular the reticular materials composed of mixtures of polypropylene and polyglactin.

Materials of organic origin that could be used according to the invention are for example membrane of bovine pericardium, human fascia lata, acellular matrix of pig collagen, and submucosa of pig small intestine, suitably treated so as to be sterile and unable to transmit animal pathologies, and to remain more or less unaltered over time.

Examples of commercial product of organic origin that could be used according to the invention are for example membrane of bovine pericardium treated with glutaraldehyde and heparin, produced by Shelhigh and marketed under the name Dome Pericardial Patch No-React® Treated, pig intestine submucosa produced by DePuy OrthoTech and known by the trade name SIS (small intestine submucosa), or reticular porcine collagen marketed by Bard under the name Pelvicol®.

The materials of organic origin are preferably used in the realisation of the present device as they are generally well tolerated by the organism, they do not give foreign body reactions, they are soft and impalpable and there is minimum risk of erosion of the tissues with which they come in contact.

The dimensions of the holes in the materials that may be used according to the invention have a diameter preferably comprised between 0.01 cm and 0.05 cm

and more preferably 0.03 cm, at a distance from each other preferably of between 0.06 and 0.1, and more preferably 0.08.

The present device is applied by surgery; during surgery, the habitual means of access is the vagina, with an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus.

Through the front vaginal wall the tendinous arch of the levator ani is penetrated, which is opened bilaterally for about 2 cm, and on which the two arms E are fixed respectively on the right and on the left.

The two rear arms F are then passed by the sides of the neck of the uterus, one on the right and one on the left, and are laid until the central part B surrounds the neck of the uterus. The right and the left half of the rear portion of the device are rejoined in the centre with two stitches and the rear arms are fixed bilaterally to the sacrospinous ligament or to the iliococcygeal muscle. At the end of the operation the device, anchored by means of the four arms to the tendinous arch of the levator ani and to the sacrospinous ligament (or to the iliococcygeal muscle), is at the normal anatomical level of the levator ani muscle. Consequently, also the organs resting on it, the bladder at the front (cystocele), the neck of the uterus in the centre (hysterocele, the rectum at the rear (enterocele), are returned to their correct anatomical plane above said muscle.

The operation can also be carried out by fixing first the two rear arms, using the device in which the cleft extends longitudinally from the central hole, cutting the front portion A.

Alternatively, the device according to the invention may be used which has the cleft H both in the front part and in the rear, and is therefore composed of two specular halves; in this case the operation is carried out by fixing first one half through the two front and rear arms and then the other half; the two halves already fixed both at the front and at the rear are then rejoined on the front portion A and on the rear portion D, taking care to position the neck of the uterus in the central hole U.

In the case of the device with a horizontal cleft, the procedures for passing around the neck of the uterus are the same as described above for the devices with a longitudinal cleft, and the suture of the cut of the device will be in a lateral position.

In patients without uterus, the operation may be carried out using the device represented in Figure 3, fixing first the front arms and then the rear arms, or vice versa.

Moreover, in patients suffering of a partial prolapse of pelvic organs, the operation may be carried out by using the device illustrated in Figure 4; in this case the vaginal surgery procedure comprises making an incision extending from the front vaginal wall to the cervix; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear short arms to the neck of the uterus.

All the cases described above may also be realised by means of "tension free" operations, in which the present device is positioned inside the vaginal cavity without fixing it with stitches, but only making dissections in the tendinous arch of the levator ani which guarantee the positioning of the front arms E. In this type of "tension free" operation the device according to the invention must have the opening of the front arms, represented in the figures by the length a-a, between 11 and 15 cm; moreover, it is preferable to use devices made of polypropylene and similar.

Moreover, as well as by the only vaginal approach, the operation may be carried out with a mixed vaginal/abdominal or vaginal/laparoscopical approach, or by means of mini-invasive surgery.

The invention being as described, it is clear that this device may be modified in various ways; these modifications are not to be considered as divergences from the spirit and from the prospects of the invention and all those modifications which would appear evident to an expert in the field are included within the scope of the following claims.

CLAIMS

1. A flat implantable device made of material with a reticular or laminar structure for supporting the female pelvic organs, characterised in that it has a central body with a trapezoid shape having four arms, in which may be distinguished:

- a front portion corresponding to the smaller base of the trapezium, from the ends of which branch off in opposite directions two arms coaxial with each other and parallel to said smaller base;
- a central portion corresponding to the central part of the trapezium;
- a rear portion corresponding to the larger base of the trapezium, from the ends of which branch off two arms diverging from each other and parallel to the sides of the trapezium.

2. The device according to claim 1, wherein said central portion has a central hole.

3. The device according to claim 2, wherein from said central hole starts a cleft which longitudinally cuts the rear portion of said central body.

4. The device according to claim 2, wherein from said central hole starts a cleft which longitudinally cuts the front portion of said central body.

5. The device according to claim 2, wherein from said central hole starts a cleft which longitudinally cuts both the front portion and the rear portion of said central body.

6. The device according to claim 2, wherein from said central hole starts a cleft which transversely cuts the right central portion of said central body.

7. The device according to claim 2, wherein from said central hole starts a cleft which transversely cuts the left central portion of said central body.

8. The device according to one of the claims 1-7, wherein said material with a reticular or laminar structure is selected from the group consisting of materials of organic origin and materials of a synthetic nature.

9. The device according to claim 8, wherein said material of organic origin is selected from the group consisting of membrane of bovine pericardium, human fascia lata, acellular matrix of pig collagen, and submucosa of pig small intestine.

10. The device according to claim 9, wherein said membrane of bovine pericardium is treated with glutaraldehyde and heparin.

11. The device according to claim 8, wherein said material of a synthetic nature is selected from materials based on single-filament polypropylene.

12. The device according to claim 8, wherein said material of synthetic origin is a mixture of polypropylene and polyglactin.

13. The device according to claim 8, wherein said material has holes having diameter comprised between 0.01 cm and 0.05 cm, at a distance from each other of between 0.06 and 0.1.

14. The device according to claim 8, wherein said material has holes having diameter of 0.03 cm, at a distance from each other of 0.08.

15. The device according to claim 1, wherein:

- the length a-a of the front arms is between 8.0 and 15 cm;
- the length b-b of the front portion is between 2.5 and 6.0 cm;
- the length c-c of the front portion is between 3.0 and 6.0 cm;
- the width b-c of the front arms is between 1.0 and 3.0 cm;
- the length d-y of the front portion is between 2.5 and 6.5 cm;
- the total length d-z of the device is between 4 and 8 cm;
- the length e-f of the rear portion is between 1.8 and 4.0 cm;
- the distance h-h between the rear arms is between 1.5 and 7.0 cm;
- the distance g-g between the rear arms is between 4.9 and 10 cm;
- the distance i-i between the rear arms is between 4.5 and 10.5 cm;
- the length h-i of the rear arms is between 1 and 3 cm.

16. The device according to claim 15, wherein:

- the length a-a of the front arms is 10 cm;
- the length b-b of the front portion is 3.8 cm;
- the length c-c of the front portion is 3.8 cm;
- the width b-c of the front arms is 2.0 cm;
- the length d-y of the front portion is 4.0 cm;
- the total length d-z of the device is 6 cm;
- the length e-f of the rear portion is 2.7 cm;
- the distance h-h between the rear arms is 5.0 cm for patients with a large body size and 3.5 cm for patients with a small size;

- the distance g-g between the rear arms is 8.0 cm for patients with a large body size and 6.9 cm for patients with a small size;
- the distance i-i between the rear arms is 8.5 cm for patients with a large body size and 6.5 cm for patients with a small size;
- the length h-i of the rear arms is 1.5 cm.

17. The device according to claims 1 or 2, wherein:
- the length a-a of the front arms is between 8.0 and 15 cm;
- the length b-b of the front portion is between 2.5 and 6.0 cm;
- the length c-c of the front portion is between 3.0 and 6.0 cm;
- the width b-c of the front arms is between 1.0 and 3.0 cm;
- the length d-y of the front portion is between 2.5 and 6.5 cm;
- the total length d-z of the device is between 11 and 15 cm;
- the distance y-x in the central hole U is between 0.6 and 1.6 cm;
- the distance x-e in the central hole U, the same as or different from the distance y-x, is between 0.6 and 1.6 cm;
- the length e-f of the rear portion is between 1.8 and 4.0 cm;
- the distance h-h between the rear arms is between 1.5 and 7.0 cm;
- the distance g-g between the rear arms is between 4.9 and 10 cm;
- the distance i-i between the rear arms is between 4.5 and 10.5 cm;
- the length h-i of the rear arms is between 2.5 and 6.5 cm.

18. The device according to claim 17, wherein:
- the length a-a of the front arms is 10 cm;
- the length b-b of the front portion is 3.8 cm;
- the length c-c of the front portion is 3.8 cm;
- the width b-c of the front arms is 2.0 cm;
- the length d-y of the front portion is 4.0 cm;
- the total length d-z of the device is 12 cm;
- the distance y-x in the central hole U is 1.1 cm;
- the distance x-e in the central hole U is 1.1 cm;
- the length e-f of the rear portion is 2.3 cm;
- the distance h-h between the rear arms is 5.0 cm for patients with a large body size and 3.5 cm for patients with a small size;

- the distance g-g between the rear arms is 7.6 cm for patients with a large body size and 6.0 cm for patients with a small size;
- the distance i-i between the rear arms is 8.5 cm for patients with a large body size and 6.5 cm for patients with a small size;
- the length h-i of the rear arms is 4.5 cm.

19. Method for surgically implanting the flat implantable device as described in claim 1 in a patient suffering of a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

20. Method for surgically implanting the flat implantable device as described in claim 2 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

21. Method for surgically implanting the flat implantable device as described in claims 3 or 4 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

22. Method for surgically implanting the flat implantable device as described in claim 5 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

23. Method for surgically implanting the flat implantable device as described in claims 6 or 7 in a non-hysterectomised patient suffering a prolapse of the vaginal vault or partial or total prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

24. Method according to claims 19 or 20, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

25. Method according to claim 24, wherein, when the said device is inserted into the vaginal cavity of the patient by means of "tension free" vaginal surgery, the said device is positioned inside the vaginal cavity without fixing it, but only making dissections in the tendinous arch of the levator ani which guarantee the positioning of the front arms of the said device.

26. Method according to claim 21, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two rear arms or the two front arms of the said device in which the cleft extends longitudinally from the central hole respectively on the right and on the left on the said opened tendineous arch; passing respectively the two front arms or rear arms by the sides of the neck of the uterus, one on the right and one on the left until the central part of the said device surrounds the neck of the uterus; rejoining the right and the left half of respectively the front or the rear portion of the device in the centre with two stitches; and

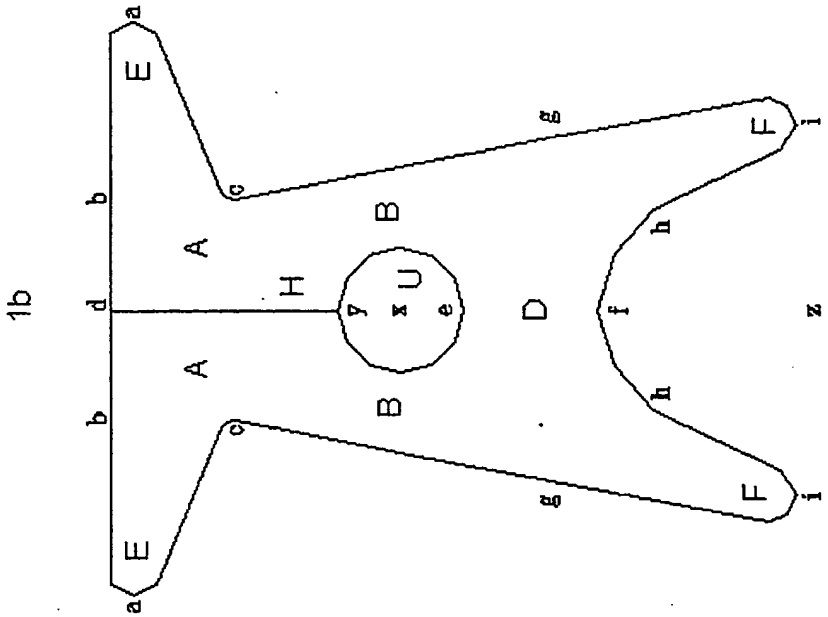
bilaterally fixing the front arms or the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

27. Method according to claim 22, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing first one half of the said device through the two front and rear arms and then the other half respectively to the opened tendineous arch and to the sacrospinous ligament or to the iliococcygeal muscle; rejoining the two halves already fixed both at the front and at the rear on the front portion and on the rear portion, taking care to position the neck of the uterus in the central hole.

28. Method according to claim 23, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the rear wall, excluding the neck of the uterus, if present; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two rear arms or the two front arms of the said device in which the cleft transversely cuts respectively the right or the left central portion of said central body on the said opened tendineous arch; passing respectively the two front arms or rear arms by the sides of the neck of the uterus, respectively both on the left or on the right until the central part of the said device surrounds the neck of the uterus; rejoining the said cleft in the centre with two stitches; and bilaterally fixing the front arms or the rear arms to the sacrospinous ligament or to the iliococcygeal muscle.

29. Method for surgically implanting the flat implantable device as described in claims 15 or 16 in a patient suffering of a partial prolapse of pelvic organs through the vagina, comprising inserting the said device into the vaginal cavity of the patient by means of a surgical approach, possibly "tension free", selected from vaginal surgery, mixed vaginal/abdominal surgery, vaginal/laparoscopical surgery, and mini-invasive surgery.

30. Method according to claims 29, wherein, when the said device is inserted into the vaginal cavity of the patient by means of vaginal surgery, said method comprises: making an incision extending from the front vaginal wall to the cervix; penetrating the tendinous arch of the levator ani through the front vaginal wall; bilaterally opening said tendineous arch for about 2 cm; fixing the two front arms of the said device respectively on the right and on the left on the said opened tendineous arch; and bilaterally fixing the rear arms to the neck of the uterus.



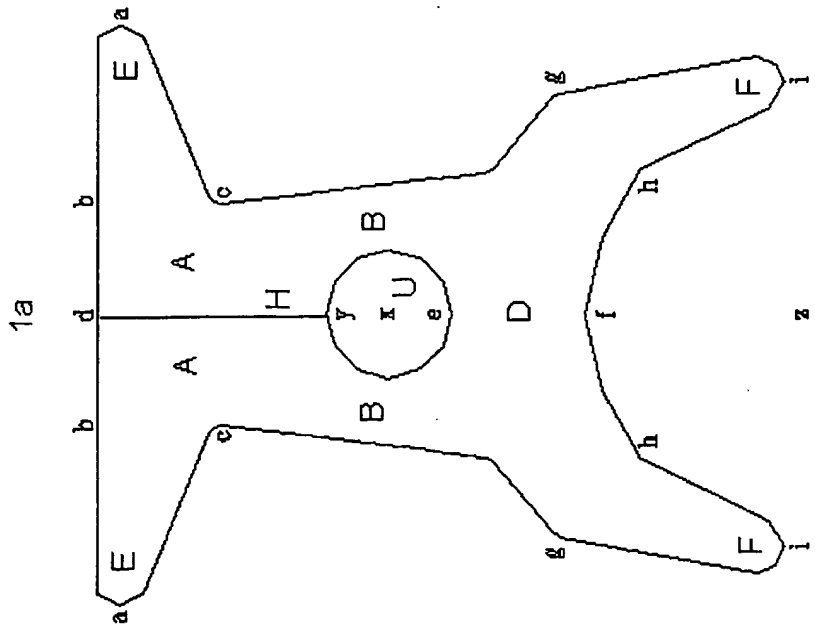
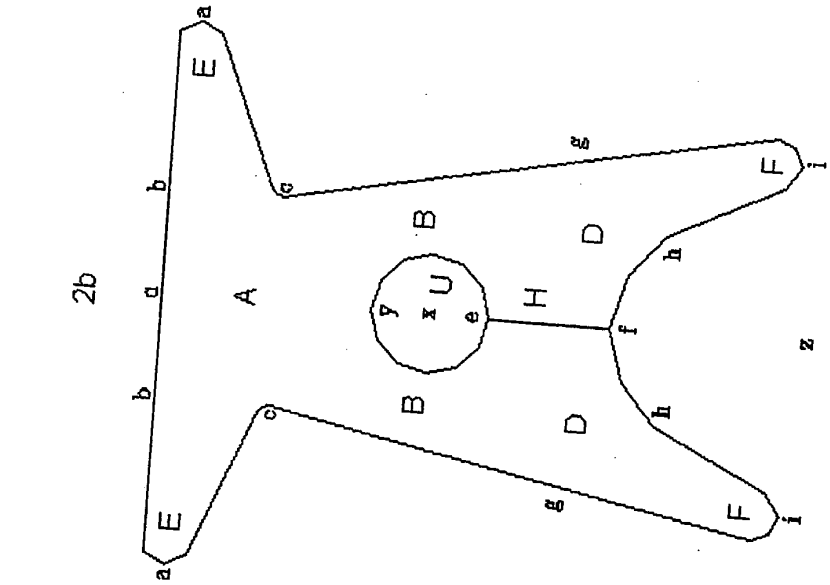


Figure 1



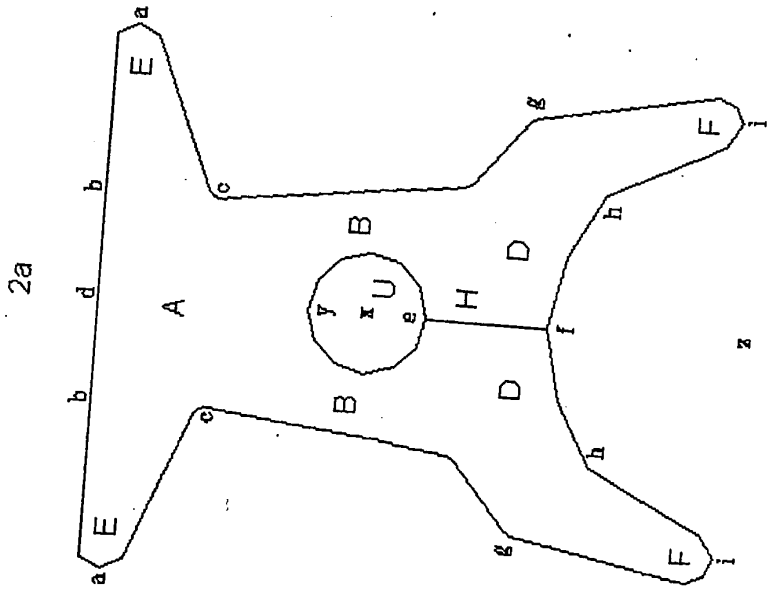
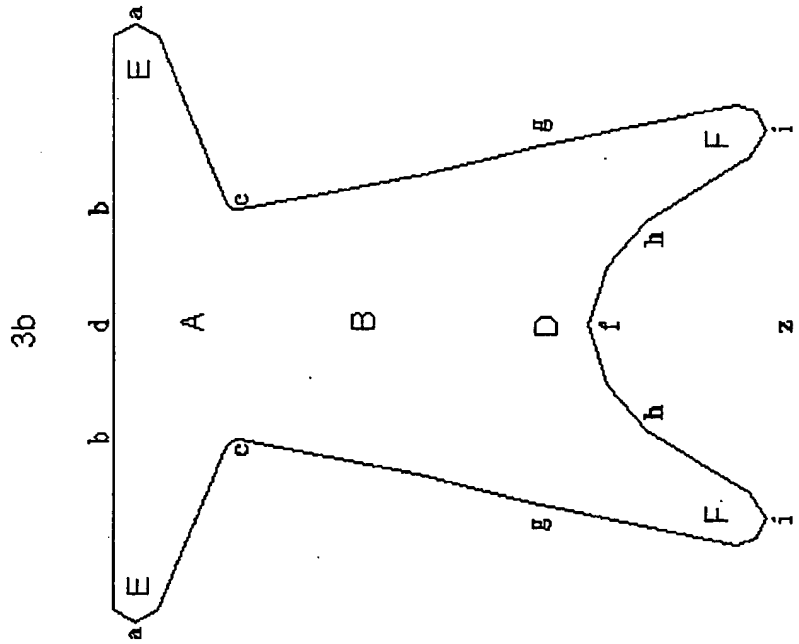


Figure 2



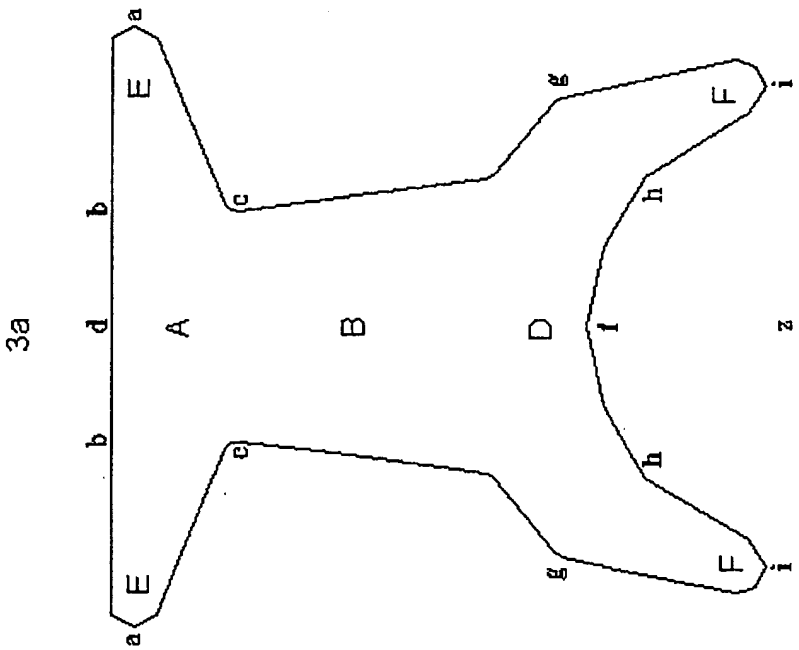


Figure 3

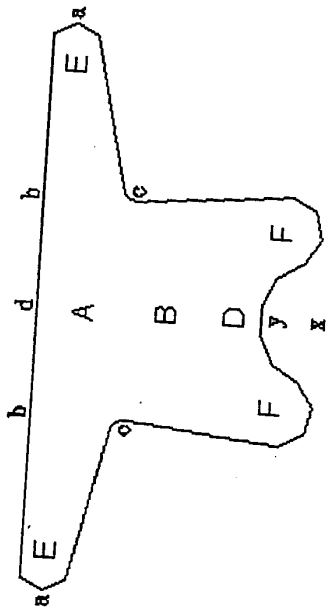


Figure 4

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/08546

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 774 240 A (ETHICON INC) 21 May 1997 (1997-05-21) figure 1 column 1, line 44 - line 56	1,8-14 2-7, 15-18
X	US 2002/099259 A1 (ANDERSON KIMBERLY A ET AL) 25 July 2002 (2002-07-25) figure 41 paragraph '0246!	1
A	WO 00 64370 A (GASTON RICHARD PIERRE ;SOFRADIM PRODUCTION (FR)) 2 November 2000 (2000-11-02) figure 1	1-18

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
26 November 2003	03/12/2003

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Franz, V

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
PCT/EP 03/08546

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 042 534 A (GELLMAN BARRY N ET AL) 28 March 2000 (2000-03-28) figure 10A	1-18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 03/08546

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19-30
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/EP 03/08546

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0774240 A	21-05-1997	DE 19544162 C1	24-04-1997
		BR 9605581 A	18-08-1998
		CA 2190449 A1	18-05-1997
		DE 69626604 D1	17-04-2003
		EP 0774240 A1	21-05-1997
		JP 9201376 A	05-08-1997
		US 5840011 A	24-11-1998
US 2002099259 A1	25-07-2002	CA 2434027 A1	01-08-2002
		EP 1353600 A2	22-10-2003
		WO 02058565 A2	01-08-2002
		US 2003065246 A1	03-04-2003
		US 2003130670 A1	10-07-2003
		CA 2403687 A1	01-08-2002
		CA 2404459 A1	15-08-2002
		CA 2434461 A1	01-08-2002
		CA 2434463 A1	01-08-2002
		EP 1353597 A1	22-10-2003
		EP 1353601 A1	22-10-2003
		EP 1353598 A1	22-10-2003
		EP 1353599 A2	22-10-2003
		US 2002147382 A1	10-10-2002
		WO 02058562 A1	01-08-2002
		WO 02062237 A1	15-08-2002
		WO 02058563 A1	01-08-2002
		WO 02058564 A2	01-08-2002
		US 2003045774 A1	06-03-2003
		US 2003050530 A1	13-03-2003
		US 2002099258 A1	25-07-2002
		US 2002107430 A1	08-08-2002
		US 2002151762 A1	17-10-2002
WO 0064370 A	02-11-2000	FR 2792824 A1	03-11-2000
		EP 1171055 A1	16-01-2002
		WO 0064370 A1	02-11-2000
		JP 2002541971 T	10-12-2002
US 6042534 A	28-03-2000	AU 6329598 A	08-09-1998
		DE 69808614 D1	14-11-2002
		DE 69808614 T2	18-06-2003
		EP 0983033 A1	08-03-2000
		JP 2001511685 T	14-08-2001
		WO 9835632 A1	20-08-1998